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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,795	11/12/2003	David Francis Capes	P-4364PIP1C1C1	7190
26253	7590	05/15/2007	EXAMINER	
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			STIGELL, THEODORE J	
		ART UNIT		PAPER NUMBER
		3763		
		MAIL DATE		DELIVERY MODE
		05/15/2007		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,795	CAPES ET AL.	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) 9-12 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/12/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

Claim Objections

Claims 9-12 are objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification. There is no disclosure in the specification of what structural elements comprise a means for allowing said connection to break by application of a breaking force and a means for preventing the removal of the needle assembly.

Appropriate correction is required.

Claims 10-11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. There is no disclosure of equivalents in the specification for the means for allowing the connection to break and for the means for preventing removal of the needle assembly. The Examiner is interpreting these means to include the structure defined in claims 10 and 11. Therefore, the limitations of claims 10 and 11 are already being read into independent claim 9 so claim 10 and 11 fail to further limit claim 9.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sultan (4,973,309). Sultan discloses a syringe (1) comprising: a barrel (2) having a fluid chamber, a proximal end, a distal end and an elongated tip (30) extending from said distal end having a passageway therethrough in fluid communication with said chamber, a collar (31) surrounding said tip, and at least one deflectable locking tab (32) projecting radially inwardly from said collar, a needle assembly (9) including a cannula (33) having a proximal end, a distal end and a lumen therethrough, a hub (34) having an open

proximal end with a cavity therein, and a distal end joined to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, an outside surface of said hub, said needle assembly being connected to said barrel so that said elongated tip of said barrel is in said cavity of said hub and said outside surface on said hub is adjacent to said locking tab so that said locking tab prevents removal of said needle assembly from said barrel through contact between said locking tab and said outside surface of said hub, said locking tab being configured to allow assembly of the needle assembly to said barrel through axial motion of the hub toward the barrel; and a plunger (4) including an elongated plunger rod having a longitudinal axis, a proximal portion (plunger rod) and a distal portion (3) connected by a breakable connection, said distal portion including a stopper (3) slidably positioned in fluid-tight engagement with an inside surface of said chamber for drawing fluid into and out of said chamber by movement of said plunger relative to said barrel, said breakable connection being strong enough to hold said proximal portion and said distal portion together during normal use of said syringe and breakable upon application of an additional force to said proximal portion, wherein one of said proximal portion and said distal portion includes an axial projection (5) having a plurality of transverse protuberances projecting therefrom, said protuberances being connected to the other of said proximal portion and said distal portion, said breakable connection being on said protuberances, wherein the at least one deflectable locking tab comprises a plurality of locking tabs, wherein the tabs are cantilevered members extending radially inward and proximally from the collar.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sultan (4,973,309) in view of Johnston et al. (4,027,669). Sultan discloses a syringe assembly designed to prevent the reuse of the assembly. Sultan discloses most of the limitations recited by the Applicant but fails to teach a fracturable section on the hub. Johnston et al. discloses a syringe assembly with a fracturable section on the hub to help in the destruction of the syringe to prevent reuse of the same needle, which is dangerous to personal and public safety. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hub of Sultan with the feature of Johnston to create a more full-proof one-use syringe.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Theodore J. Stigell
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Matthew DeSanto
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5/9/07